REMARKS

Entry of this Amendment is proper under 37 C.F.R. § 1.116 because the Amendment places the application in condition for allowance for the reasons discussed herein or will reduce the number of issues on appeal should an appeal be necessary. This Amendment does not raise any new issues requiring further search and/or consideration as the amendments amplify issues previously discussed throughout prosecution. Entry of the Amendment is thus respectfully requested.

Claims 9 and 11 have been amended to correct an error introduced in the preceding amendment, now again reciting "PG4 monoclonal antibody" instead of "anti-PG4 monoclonal antibody." Claim 9 has been amended to restore recitation of the term "normal skin" in the preamble. Support for the amendments may be found in the specification, for example as previously described for claims 9-13.

Claim 14 has been added as a copy of claim 9 with the difference that claim 14 recites that antibody binding indicates "a papillary fibroblast population," copied from the preamble thereof and does not recite "normal skin." New claim 15 is a copy of claim 10 that correspondingly depends from claim 14. Support for the amendment can be found throughout the specification and in the drawing.

No new matter has been added. Applicants reserve the right to file a continuation or divisional application directed to any subject matter that may have been canceled by the present amendment.

Deposit Requirement

The Examiner has asserted that the PG4 antibody is required for the practice of the claimed invention and that a deposit of the hybridoma cell line producing the antibody is required to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph.

Applicants traverse the requirement that a deposit of the antibody or cell line that produces the PG4 antibody is necessary. As long as an antibody is known and readily available, no deposit is required. M.P.E.P. § 2404.01. Factors that may be used as indicia that the material is known and readily available to the public includes reference to the material in printed publications. *Id.* Moreover, where a biological material can be made without undue experimentation, a deposit is not necessary. M.P.E.P. § 2404.02.

The method of making, screening and characterizing the subject antibody is described in detail by Sorrell et al., *Histochemical Journal* 31:549-558 (1999) (previously submitted) such that one skilled in the art would be able to make an antibody having the characteristics of PG-4 by routine methods as described. Thus, one skilled in the art may readily obtain an antibody having the characteristics of PG-4 by reference to the guidance of the present specification and Sorrell et al.

The Examiner asserts that it is unclear whether the isotyping kit mentioned by Sorrell et al. is available to the public. It is clear from the article that that isotyping kit is a commercially available product, as the vendor from which the kit was obtained is provided by Sorrell et al. Moreover, for such a routinely used kit, one skilled in the art would be aware of suitable substitutes. Thus, the availability of the kit does not pose an obstacle to the enablement of the claimed invention.

Applicants respectfully maintain that the conditions set forth in M.P.E.P. § 2404 are satisfied such that a deposit is not required and request withdrawal of the requirement of a

deposit. Even if the requirement is not withdrawn, Applicants request that the issue be held in abeyance until otherwise allowable subject matter is agreed upon.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 9-13 have been rejected under 35 U.S.C. § 112, first paragraph as allegedly not enabled and as allegedly containing new matter for recitation of "anti-PG4 monoclonal antibody."

The recitation of "anti-PG4 monoclonal antibody" was introduced by mistake in amending the claims. By the present amendment, the clams 9 and 11 have been amended to read "PG4 monoclonal antibody" as described in the specification.

Withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 9-13 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. With respect to claim 9, it has been alleged that "normal skin" is vague and indefinite. By the present amendment, claim 9 is amended to restore recitation of the term "normal skin" in the preamble thereof so as to better describe the goal of the method.

Applicants respectfully submit that the metes and bounds of "normal skin" as recited in claim 9 would be apparent to one skilled in the art from the specification taken together with knowledge and common usage in the art. Furthermore, the meaning of normal skin with regard to the presently claimed method is clearly described in the specification. For example, at page 1, line 13 to page 2, line 21, normal skin is described, summarized as "in normal skin, the dermis comprises of at least two fibroblast populations." At page 3, lines 2-4, it is

pointed out that "skin reconstructed in vitro will be all the more similar to normal skin when it includes at least two fibroblast populations." At page 4, the specification makes clear that PG4 antibody binding is a "marker" for a biological element which is present in normal skin. Therefore, one of skill in the art would understand the metes and bounds of the term "normal skin" as it applies in the context of claims 9-10.

Claims 11-13 do not recite "normal skin." The Office action provides no other apparent basis for the rejection, and it is not clear how the rejection could be applied to claims 11-13. Applicants respectfully submit that the metes and bounds of claims 11-13 would be understood by one skilled in the art. Accordingly, withdrawal of the rejection is respectfully requested.

Claims 14-15 have been added as copies of claims 9-10, but recite that said binding indicates "a papillary fibroblast population," rather than "normal skin."

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

In the event any further fees are due to maintain pendency of this application, the Examiner is authorized to charge such fees to Deposit Account No. **02-4800**.

Respectfully submitted,
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